UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

IN RE PHARMACEUTICAL INDUSTRY AVERAGE WHOLESALE PRICE LITIGATION	MDL NO. 1456 Civil Action No. 01-12257-PBS
THIS DOCUMENT RELATES TO ALL CLASS ACTIONS	Hon. Patti B. Saris Chief Mag. Judge Marianne B. Bowler

TRACK 1 DEFENDANTS' MEMORANDUM IN RESPONSE TO PLAINTIFFS' MOTION TO SUPPLEMENT THE RECORD

[REDACTED VERSION]

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Although the Court has granted plaintiffs' motion to supplement the record with so-called "new evidence," the Court should not be deceived into believing that the documents attached to plaintiffs' motion are "new." In fact, in nearly every case, the documents referenced in the motion were made available and produced to plaintiffs before the close of briefing on the class certification motion. Thus, plaintiffs' motion is markedly different from the Track 1 Defendants' earlier motion to supplement the record, which was based on information that did not become available until after the class certification hearing.

Furthermore, unlike defendants' motion, plaintiffs' motion is a transparent attempt to prop up old arguments that were fully addressed in the context of the class certification motion. Thus, whereas defendants' motion presented genuinely new evidence on a discreet issue as to which evidence had not previously been available – namely the difficulty of determining whether a particular patient made payments based on AWP – plaintiffs' motion merely piles on cumulative (and cherry-picked) support for the discredited and simplistic contention that individual issues do not predominate because of the alleged "uniformity of the use of AWP."

As we discuss in the Appendix hereto, the documents attached to plaintiffs' motion do not support plaintiffs' class certification arguments. Rather, they simply confirm that payer contracts frequently express the negotiated amount to be paid for prescription drugs in terms of AWP minus a percentage discount. This fact in no way undermines defendants' point that individual issues predominate. Whether AWP is referenced in a contract is not the salient issue for class certification. The relevant questions are what do payers understand AWP to mean, why do they pay the amounts that they pay, and do they have any uniform expectation as to the difference between AWP and average sales price – all of which can only be determined on an individualized basis.

Finally, in connection with the motion to supplement, plaintiffs take another unfair shot at the Court's expert, Dr. Ernst Berndt, whom they falsely accuse of industry bias. This allegation, and the equally offensive suggestion that Dr. Berndt was somehow misled by defendants' expert, Steven J. Young, is outrageous and inexcusable. So too is the argument that defendants' tutorial expert, Dr. Gregory K. Bell, engaged in improper conduct with respect to work he performed for Bristol-Myers Squibb Co.

A. The "New Evidence" is Not "New"

Plaintiffs' styled their motion as a motion to supplement the record with "new evidence." As set forth in the accompanying declaration of Andrew D. Schau, the documents attached to plaintiffs' motion are not "new." Rather, with only two exceptions, the documents were made available or produced to plaintiffs before the close of briefing and argument on plaintiffs' class certification motion.

B. Plaintiffs Mischaracterize Defendants' Arguments and Disregard that the New Discovery Undermines Their Class Certification Motion

Defendants have never denied that payers frequently express the negotiated reimbursement amount in terms of a discount off of AWP, e.g., AWP-11%, AWP-15%, AWP-18%, etc. That does not mean, however, that pharmaceutical reimbursement is "uniformly" based on AWP, or that a reference to AWP in a reimbursement formula means that the AWP itself determines the overall rate of reimbursement. Nor does it mean that individual issues do not predominate over common issues.

First, defendants thoroughly documented in their submissions opposing class certification that individual payers do not a share a single "market expectation" regarding the relationship between AWP and acquisition cost, in part because knowledge levels differ, contracting objectives differ, and acquisition costs vary widely by class of trade. The truly "new" discovery – obtained within the last two weeks – further demonstrates that health plans do not uniformly expect AWP to bear a predictable relationship to acquisition costs.[1] Thus, causation and injury cannot possibly be established on a class-wide basis.

Second, the new evidence also reinforces defendants' showing that reimbursement for prescription drugs is based on a web of proprietary contracts that are negotiated individually and competitively, based on a myriad of factors, among manufacturers, wholesalers, pharmacies, pharmacy benefit managers, physicians, and third-party payers. With respect to physician reimbursement, for example, Aetna's counsel recently stipulated at a deposition that "the particular reimbursement set for any particular physician varies depending

[1] [redacted]

upon the hundreds of factors and information and considerations that are involved in any particular doctor Aetna negotiates with."[2] The recent depositions also confirm that payers reimburse physician-administered drugs using methodologies other than AWP.[3] And they have shown that even when reimbursement is expressed in terms of AWP, the role that AWP plays in setting the overall reimbursement amount will vary from payer to payer and contract to contract.[4]

At bottom, payers are interested in lowering their reimbursement costs on an aggregate basis. The negotiated rate of reimbursement for drugs is simply one part of a series of tradeoffs emerging out of the overall competitive dynamic. The effect of AWP, if any, cannot be determined "formulaically," as plaintiffs suggest, but requires close analysis of the negotiations surrounding each individual contract.

2 [redacted]

3 [redacted]

4 [redacted]

Third, plaintiffs' attempt to shoehorn dozens of companies and hundreds of drugs into a single case raises a host of individualized fact determinations concerning the usage of AWP, e.g., whether the AWP was "controlled" by the defendant, whether it was "manipulated," whether it was "marketed," whether it was "inflated," etc. Plaintiffs' belated admission, per Dr. Rosenthal, their tutorial expert, that "for 99% of prescription drugs AWP works and is not being challenged," and their concomitant refusal to identify any of the drugs that allegedly were "unaffected by the AWP scheme and fraud" (see Dkt. No. 1601), means that the parties and the court will be required to analyze the appropriateness of class certification on a company-by-company and drug-by-drug basis.

Fourth, as defendants documented in their own motion to supplement the record, experience in the real world shows that it can be extremely difficult and time consuming to determine whether a particular patient actually paid for a drug on the basis of AWP.[5] Plaintiffs are not correct to assert that the methodology utilized to reimburse drugs may be readily determined from the face of the reimbursement contracts.[6]

[5] In their response to defendants' motion to supplement the record on this issue, plaintiffs argued that Judge Stearns had already rejected this argument. In fact, Judge Stearns never had to reach the issue because the settlement class in that case consisted of all persons and entities who "made Lupron® purchases." In re: Lupron® Mktg. and Sales Practices Litigation, MDL No. 1430 (Nov. 24, 2004 Order). Claimants to the settlement fund were not required to demonstrate that their Lupron® purchases were based on AWP.

[6] 

C. Plaintiffs Mischaracterize the Allegedly "New Evidence" They Proffer Concerning the Use of AWP

The documents attached to plaintiffs' motion do not undermine the foregoing arguments or the opinions expressed by defendants' experts. In fact, as described in the Appendix hereto, the "new evidence" annexed to plaintiffs' motion simply underscores defendants' point that drug reimbursement is highly variable and complex, and not susceptible to class treatment.

D. Plaintiffs Mischaracterize the "New Evidence" Concerning Dr. Bell

Plaintiffs' unwarranted attack on Drs. Berndt and Bell demonstrates the depths to which they are willing to go in order to rescue their untenable position. Plaintiffs begin by stating: "As they did with Professor Berndt, defendants hid from the Court their tutorial expert's deep ties to the industry." (Pltfs' Mem. at 8.) As we have previously demonstrated (Dkt. No. 1507), Professor Berndt fully disclosed his work for both plaintiffs and defendants, and he was plaintiffs' choice for the independent expert. Similarly, Dr. Bell stated in his tutorial: "In my capacity as a strategy consultant, I've led many projects involving pricing and contracting strategy in the pharmaceuticals industry."[7]

One of the documents that plaintiffs attribute to Dr. Bell is not even a CRA document; it is a BMS document which states that Dr. Bell – along with 34 other people – were members of the Tequin pricing team.[8] To make matters worse, a chart that plaintiffs attribute to Dr. Bell (Pltfs' Mem. at 4-5) was not in fact created by Dr. Bell. Furthermore, plaintiffs

[7] It is well-established that a person's involvement in subject matter of the case does not preclude him from testifying as an expert. See, e.g., Den Norske Bank AS v. First Nat'l Bank of Boston, 75 F.3d 49, 57-58 (1st Cir. 1996) (employee permitted to testify as an expert); Shane v. Shane, 891 F.2d 976, 982 (1st Cir. 1989) (the fact that expert had a "personal interest" in the subject matter did not preclude his testimony). As the Seventh Circuit has observed: "A litigant, or a litigant's CEO, or sole stockholder, or mother, or daughter is not, by reason of his or her or its relation to the litigant, disqualified as an expert witness." Braun v. Lorillard Inc., 84 F.3d 230, 237-38 (7th Cir. 1996).

[8] Pltfs' Mem. App. C.3 at BMS/AWP/01278484.

misrepresent the contents of the chart, leaving out a reference to Tequin prices which reveals that the "spread" for that drug was lower than three of the four drugs with which it was compared.[9]

Plaintiffs' reliance on various documents relating to "Paraplatin deconversion" is even more misleading. (Pltfs' Mem. at 8-9.) Paraplatin (or carboplatin), a BMS chemotherapy drug, was a successor product to Platinol, also a BMS chemotherapy drug. When a less expensive generic version of Platinol became available, BMS was concerned that doctors who were using Paraplatin would return, or "deconvert," back to Platinol, even though Paraplatin was therapeutically superior. That is why Dr. Bell made the totally innocent comment, depicted by plaintiffs in the most sinister light, that deconversion "will be driven by an economic rationale." (Pltfs' Mem. at 8.)

Plaintiffs point to a "discussion outline" dated July 2, 1999, which contains the phrases "[a]quisition cost and AWP" and "AWP and spread opportunities" to argue that Dr. Bell "emphasize[d] the use of marketing spread as a tactic to convert doctors to BMS' paraplatin." (Pltfs' Mem. at 8.) That document says nothing of the sort. It simply states that these issues were topics for discussion. There are no recommendations from Dr. Bell or CRA.

Plaintiffs also point to the phrase "[n]o printed materials" in a second discussion outline dated August 17, 1999, and assert that Dr. Bell "advise[d]" BMS not to create a written record because he was "aware of the questionable legality of this conduct." (Pltfs' Mem. at 8-9.) The document actually states:

"Economic Issues to be discussed in a low key manner

- No printed materials

[9] Plaintiffs also claim that Dr. Bell "recommended pricing based on AWP in order to win in the retail market," citing BMS/AWP/01278505. That chart is also not Dr. Bell's, and it demonstrates that the AWPs of comparable drugs vary from $3.42 to $8.00 a pill, the average prescription cost varies from $44 to $80.22, and there is no constant relationship between AWP and average cost – further demonstrating that this case cannot be tried on a class basis.

- Respond to physician concern
- Maintain the 'high road' – officially promoting Paraplatin based on efficacy, tolerability and quality of life."

(Id. at App. C.2 at BMS/AWP/01233134.) As this passage makes clear, far from advocating marketing of the spread, Dr. Bell was suggesting that economic issues be discussed in a "low key manner," without resorting to written sales materials, so that "efficacy, tolerability and quality of life" issues could be emphasized.

Finally, plaintiffs proffer CRA's final "findings and recommendations," dated October 13, 1999, without mentioning to the Court that they do not contain any of the statements in the previous "discussion" outlines with which plaintiffs take issue. (Pltfs' Mem. at 9.) This document simply states that "[t]he results of the market research clearly indicate the importance of educating at-risk physicians on the economics of Paraplatin vs. cisplatin." There is nothing wrong, let alone illegal, with responding to a customer's questions regarding the financial implications of purchasing a product.

Conclusion

Plaintiffs' "new evidence" is not "new" and it does not support plaintiffs' class certification motion.

Respectfully submitted,

ON BEHALF OF THE TRACK 1 DEFENDANTS

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Dated: August 3, 2005

Appendix

The "New Evidence"

The Novartis Document: Plaintiffs' Appendix A.1 is a Novartis document entitled "Pharmacy Benefit Report™ Facts & Figures 2004 Edition," which presents market research collected, analyzed and published by Emron, a healthcare market researcher and publisher, and was made publicly available on or about November 4, 2004. The Pharmacy Benefit Report states that, for branded products, Managed Care Organizations (MCOs) report that they most frequently reimburse pharmacies at a rate of "AWP less 15%." According to the document, reported reimbursement rates ranged from a high of AWP less 11% to a low of AWP less 18%. The document further reports that dispensing fees also varied, with some MCOs offering "performance-based" dispensing fees and others not. In the case of generic drugs, the MCOs reported using "several price bases to calculate pharmacy reimbursement," including "the Centers for Medicare and Medicaid Services' (CMS) maximum allowable cost (MAC) rate"; "the MAC rate plus a plan formula"; "a plan or PBM MAC rate," "straight AWP less discount," or another formula. If anything, the Pharmacy Benefit Report underscores the variability and complexity of drug reimbursement, not its uniformity.

The BMS Documents: Appendix A.2 is a BMS document from 2001 relating to certain chemotherapy drugs, and it reports that "[m]ost payers use AWP as a basis for calculating allowables," that "AWP can differ per the pricing source," and that the "Medicare allowable is "AWP-5%." These facts are not in dispute. The issues are what are payers' expectations as to the difference between AWP and acquisition cost and why did they choose a particular allowable amount – be it AWP minus, AWP plus or AWP.

Appendix B.9 is a single page from a document describing reimbursement in the "oncology market." That market is said to be "unique among market segments because of the role of the community-based oncologist…." The document identifies five "Key Components of

Reimbursement" including reimbursement for the "Physician Services," reimbursement for the "Administration of chemotherapy," reimbursement for the "Drug," reimbursement for "Supplies" and reimbursement for the "Facility." These BMS documents are consistent with defendants' contention that drug reimbursement is merely one part of an overall reimbursement package, the elements of which are interrelated.[10]

The AstraZeneca Documents: Appendix A.3 is an AstraZeneca document that illustrates the disparate role of AWP as it relates to patients, physicians, MCOs, hospitals, and pharmacists. The document states that AWP is of "no concern" to patients, "unless [their] co-pay is tiered based on AWP." The document further states that physicians have an interest in AWP "only as far as it impacts cash price at the pharmacy." Physicians are said to prefer "products with lower AWPs." MCOs also prefer drugs with lower AWPs because most of them reimburse pharmacies at a percentage of AWP. However, the MCO's interest in AWP is "overshadowed by [their] interest in rebates." Hospitals and related entities have "[n]o interest in AWP" and are "not impacted by AWP." Pharmacists have a "significant" interest in higher AWPs, because it is the "foundation" of reimbursement to the pharmacy. The document thus illustrates the complex and conflicting roles AWP plays in the health care system.

Appendix A.5 is an AstraZeneca document stating that "pharmacy reimbursement" for branded products is based on "standard formula with varying AWP discounts, dispensing fee and patient contribution." The document gives an example showing that a pharmacy that pays $42.50 for a drug with an AWP of $50 will break even on the cost of the drug if it is reimbursed at AWP-15%. (See Novartis document, supra, indicating that MCOs most often reimburse pharmacies at AWP-15%.)

[10] The other BMS documents are discussed in the section of the memo regarding Dr. Bell's consulting role.

Appendix B.2 is a document AstraZeneca received from a consulting firm. The consulting firm reports that payers are quite sophisticated, noting, for example, that "if payers suspect that a higher priced package is unsupported by medical justification they will reimburse at the lower price." Payers are described as being "quite diligent" in correcting for "price anomalies that result in higher reimbursement…." Indeed, payers "hunt for the least expensive per-unit AWP and reimburse providers at that price." Payers will not pay for a "more expensive product" unless the medical justification is "'compelling' when judged by an unbiased audience." This document, like Dr. Berndt's report, supports defendants' contention that payers are sophisticated and that competition is robust.

Appendix B.3 is a reimbursement guide for physicians. It reports that, in the case of Zolodex®, reimbursement payments "will differ among payers but will usually be based on the 'average wholesale price' (AWP) as listed in the *Red Book*." It also states that "most insurers will not reveal the amount that they will pay" but that the amount is "often 80 percent" of AWP. "Some payers" pay an additional fee for administration, which varies, and "[m]ost" payers will cover the office visit, but that amount too will "differ by payer." Overall, "[p]ayment amounts vary by plan." Appendix B.4 is a similar reimbursement guide that states that "private payers offer many different policies," that payments for office visits and administration "vary by the patient's specific plan," and that "[m]ost plans reimburse for ZOLADEX based on the AWP or submitted charge." Again, these documents illustrate that AWP is one component of a variable reimbursement package that differs from payer to payer.

The GSK Documents: Appendix B.5 is an internal report of a price change by a competitor that has no bearing on class certification issues. Appendix B.6 compares price and reimbursement for two drugs based on AWP. It does not purport to account for any of the other

known variations in reimbursement. Appendix B.7 is a document prepared in 1991 by a consultant. It states that payments for Zofran® "will vary depending upon the setting in which it is used." Some plans reimburse hospitals at "acquisition cost," whereas others "allow a mark-up." Physicians are reimbursed "up to" the AWP or at "actual acquisition cost, if the physician submits an invoice." Appendix B.8 compares two hypothetical reimbursement scenarios based upon whether Medicare reimburses at 80% of AWP or 80% of EAC.

The J&J Defendants' Documents: Appendix B.1 is a one-page worksheet which is part of a longer Centocor document discussing physician reimbursement for Remicade®. The worksheet enables the physician to compare her individual cost structure to her individual rate of reimbursement in order to determine whether in-office administration of Remicade will result in "income or loss." Physicians are cautioned that the analysis is complicated by "many factors, including payer mix, payer policies, office costs, and more." Appendix B.10 is an internal Ortho Biotech document that illustrates two reimbursement scenarios: Medicare reimbursement at 95% of AWP, and private payer reimbursement at 88% of AWP. Neither of these J&J company documents suggests or implies that physician payments are based solely on AWP or that reimbursement levels are unaffected by differences in payer mix and payer policies. If anything, they illustrate the opposite.

The Schering/Warrick Documents: Appendix A.4 is a hypothetical illustration that shows that AWP-based reimbursement for a generic drug can simultaneously result in a greater margin for the pharmacy and a lower reimbursement cost to the payer. Appendix A.6 is an internal memo discussing the pros and cons (from Schering's perspective) of offering rebates on Claritin® to unspecified "Medical Groups" in California. The document makes reference to the "AWP price differential between Claritin and Allegra," but that reference has nothing to do

with reimbursement. Indeed, Claritin's higher AWP in comparison to Allegra's is described as a "significant competitive disadvantage." (Plaintiffs make the opposite claim, arguing that drug companies raise AWP in order to gain a competitive advantage.)

CERTIFICATE OF SERVICE

I hereby certify that on August 3, 2005 I caused a true and correct copy of The Track 1 Defendants' Memorandum in Opposition to Plaintiffs' Motion to Supplement the Record to be served on all counsel of record by electronic service pursuant to Case Management Order No. 2 entered by the Honorable Patti B. Saris in MDL 1456.

/s/Andrew D. Schau
Andrew D. Schau